

REMARKS

Claims 22-29 are pending in the instant application. Claims 22, 25, and 28 have been amended. These amendments are supported by the application as originally filed, *inter alia*, at page 4, lines 13-17, which state: "While it had been previously found that triclosan can be particularly useful when used in conjunction with chlorhexidine, it has been further discovered that medical articles having suitable antimicrobial properties may be prepared, according to the present invention, which contain triclosan and a silver compound without chlorhexidine." The use of non-silver metals and hydrogels is supported, for example, by the instant specification at page 17 line 25 through page 18 line 14.

As such, the amendments do not constitute new matter. No claims have been added or cancelled herein. Thus, claims 22-29 will remain pending upon entry of the instant amendment.

The Examiner has stated that documents considered in connection with the parent application, i.e. serial No. 09/281,872, have also been considered in connection with the instant application. *See* Office Action dated February 24, 2003, page 2, paragraph 2. The Examiner has requested a Form PTO-1449 listing those documents. Our records indicate that such a PTO-1449 was submitted in the instant application on August 8, 2001. Nonetheless, in satisfaction of the Examiner's request, Applicants have enclosed herewith a Form PTO-1449 listing the documents considered in the parent application.

A. The Amended Claims Do Not Constitute Double Patenting

Claims 22-29 have been rejected under the judicially-created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-16 of U.S. Patent No. 6,083,208 (hereinafter "the '208 patent"), claims 1-26, 31-33, and 45-55 of U.S. Patent No. 6,106,505 (hereinafter "the '505 patent"), and claims 1-23 and 28-30 of U.S. Patent No. 5,772,640 (hereinafter "the '640 patent"). The Examiner has acknowledged that the allegedly conflicting claims are not identical. However, the Examiner has alleged that the '208 patent, the '505 patent, and the '640 patent are each "directed to a gel (polyurethane) in combination with a metal compound and triclosan" such that the instant claims are not patentably distinct. *See* Office Action dated February 24, 2003, page 2, paragraphs 3-5.

Applicants traverse these rejections and assert that instant claims 22-29 are patentably distinct from the '208 patent, the '505 patent, and the '640 patent. Claims 1-16 of the '208 patent, claims 1-26, 31-33, and 45-55 of the '505 patent, and claims 1-23 and 28-30 of the '640 patent all recite impregnation solutions that comprise **chlorhexidine**. *See e.g.* the '208 patent, claims 1 and 6 (chlorhexidine free base, chlorhexidine salt, or chlorhexidine derivative); the '505 patent, claims 1, 5, 15, 21, 31, and 45 (chlorhexidine free base); the '640 patent, claims 1, 5, 18, and 28 (chlorhexidine free base, chlorhexidine salt, or chlorhexidine derivative).

One of the novel aspects of the instant claimed invention is that "medical articles having suitable antimicrobial properties may be prepared ... which contain triclosan and a silver compound **without chlorhexidine**." *See e.g.* page 4, lines 13-17 of the instant specification (emphasis added). Medical articles prepared without chlorhexidine advantageously avoid

possible adverse reactions in individuals having a sensitivity to chlorhexidine. *See e.g.* paragraph (the instant specification at page 14 lines 17-20). The medical articles and treatment solutions recited by instant claims 22-29, as amended herein, do not include chlorhexidine. Therefore, these claims are patentably distinct over the cited patents. As the crux of the '640, '208 and '505 patents, all of which are related, involve combinations of **chlorhexidine** and triclosan, the instant claims, which are amended to exclude chlorhexidine, cannot be considered obvious.

Accordingly, the rejection should be withdrawn.

B. The Claims Are Novel Over U.S. Patent No. 5,567,495

Claims 22-29 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,567,495 to Modak et al. (hereinafter “the ‘495 patent”). The Examiner has alleged that the ‘495 patent discloses triclosan, various silver containing antibiotics, and “in addition, polyurethane, silicone, polyethylene oxide e.g., which for gels [sic], as additives to the treatment solution.” *See* Office Action dated February 24, 2003, page 3, paragraph 6. The Examiner has also alleged that the weight percents are broad and disclosed by the ‘495 patent. The Examiner has further alleged that the ‘495 patent anticipates claim 24 in that it discloses povidone iodine and claim 29 in that it discloses Teflon rings, seals, and patches that may be permanent.

Applicants traverse these rejections and assert that claims 22-29 are not anticipated by the ‘495 patent.

First, the instant claims recite a specific combination of elements, namely triclosan, a metal compound such as silver, and either a hydrogel or an anti-inflammatory agent.

The '495 patent fails to teach either specific combination. In particular, neither a hydrogel not an anti-inflammatory agent are disclosed.

Second, as noted in the foregoing section, one of the inventive aspects of the claimed medical devices is that chlorhexidine is not required. Applicants assert that the '495 patent does not anticipate claims 22-29, as amended herein, because it fails to teach the **exclusion** of chlorhexidine; rather, the use of chlorhexidine is taught as being preferred by the '495 patent.

Therefore, the '495 patent fails to teach each and every element of the claimed invention, so that it cannot anticipate any of the claims. Moreover, because critical elements of the claims are missing in the '495 patent disclosure, and because, by affirmatively teaching the use of chlorhexidine, the '495 patent teaches **away** from the instant invention, the '495 patent cannot be considered to render the claims obvious. Therefore, Applicants respectfully request withdrawal of this rejection.

Applicants believe that all pending claims are in condition for allowance and respectfully solicit favorable action on the application.

December 8, 2003

Respectfully submitted,



Lisa B. Kole
PTO Reg. No. 35,225
Attorneys for Applicants

BAKER BOTTS, L.L.P.
30 Rockefeller Plaza
New York, NY 10112
(212) 408-2500